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NATIONAL
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General

Guideline Title

Screening for prostate cancer: a guidance statement from the Clinical Guidelines Committee of the American College of Physicians.

Bibliographic Source(s)

Qaseem A, Barry MJ, Denberg TD, Owens DK, Shekelle P. Screening for prostate cancer: a guidance statement from the Clinical Guidelines Committee of the American College of Physicians. *Ann Intern Med.* 2013 May 21;158(10):761-9. [25 references] [PubMed](#)

Guideline Status

This is the current release of the guideline.

Recommendations

Major Recommendations

On the basis of the review of the available guidelines, the American College of Physicians (ACP) concludes:

Guidance Statement 1: ACP recommends that clinicians inform men between the age of 50 and 69 years about the limited potential benefits and substantial harms of screening for prostate cancer. ACP recommends that clinicians base the decision to screen for prostate cancer using the prostate-specific antigen test on the risk for prostate cancer, a discussion of the benefits and harms of screening, the patient's general health and life expectancy, and patient preferences. ACP recommends that clinicians should not screen for prostate cancer using the prostate-specific antigen test in patients who do not express a clear preference for screening.

Benefits and Harms of Screening (Prostate-Specific Antigen [PSA] Test and Digital Rectal Examination [DRE])

The modest potential mortality benefit in 1 prostate cancer screening trial with the PSA test was limited to men between the age of 55 and 69 years. Data were insufficient to reach a conclusion about the benefits or harms of screening in men aged 50 to 54 years. However, because this group has a longer life expectancy, they have more potential for long-term net benefit. The European Randomized Study of Screening for Prostate Cancer (ERSPC) study, which screened men mostly with the PSA test, showed that 1410 men would need to be screened to prevent 1 death from prostate cancer. Evidence for the benefit of DRE screening is limited, and the Prostate, Lung, Colorectal, and Ovarian (PLCO) trial, which included both PSA testing and DRE, showed no benefit. As far as mortality benefit is concerned, the evidence is inconsistent about whether screening reduces cancer-related death, and any absolute mortality risk reduction is probably small to none.

The harms of prostate cancer screening are substantial and include false alarms (suggesting that a patient may have cancer when he does not) related to high false-positive rates associated with DRE and especially the PSA test, overdiagnosis (that is, detecting cancer that will not cause future morbidity and mortality), high false-negative rates, anxiety, and discomfort. Positive screening results may lead to further testing, such as biopsies, which not only can be painful but can also lead to complications, such as infections, as well as overtreatment and the harms associated

with it. In addition, currently available treatments are associated with harms, such as urinary, gastrointestinal, and sexual problems, as well as potential cardiovascular events and death. Data from Prostate Cancer Intervention Versus Observation Trial (PIVOT) showed that men who had radical prostatectomy had an 11% increased risk for urinary incontinence and a 37% increased risk for erectile dysfunction. Harms specific to DRE include discomfort and rectal bleeding.

Shared Decision-Making Approach

Clinicians should not screen for prostate cancer in men who do not wish to make the screening decision or do not express a clear preference about screening. However, some men would still prefer to be screened because they may put more value on the possible small benefit and less value on the harms. In these circumstances, shared decision-making is important in making choices about prostate cancer screening. Clinicians should elicit patient preferences for screening during the shared decision-making process and document them in the medical record. It is important to educate the patient about the following points and document the conversation in the medical record:

1. Prostate cancer screening with the PSA test is controversial.
2. Screening with the PSA test can detect prostate cancer, but for most men, the chances of harm from screening with the PSA test outweigh the chances of benefit.
3. A small number of prostate cancer cases are serious and can cause death; however, the vast majority of prostate cancer is slow-growing and does not cause death.
4. Most men who choose not to do PSA testing will not be diagnosed with prostate cancer and will die of something else.
5. Patients who choose PSA testing are much more likely than those who decline PSA testing to be diagnosed with prostate cancer.
6. The PSA test often does not distinguish between serious cancer and nonserious cancer. However, men with markedly elevated PSA levels ($>10 \mu\text{g/L}$) may have a reduced chance of dying from prostate cancer by having surgical treatment.
7. The small potential benefit of prostate cancer screening corresponds to preventing, at most, 1 death caused by prostate cancer per 1000 men screened after 11 years of follow-up.
8. There are many potential harms of screening. There may be problems in interpreting test results: The PSA test result may be high because of an enlarged prostate but not because of cancer, or it may be low even though cancer is present. Prostate biopsy, if needed, is also not free from risk. It involves multiple needles being inserted into the prostate under local anesthesia, and there is risk for infection or clinically significant bleeding and hospitalization (1.4%). If cancer is diagnosed, it will often be treated with surgery or radiation, which are associated with risks. There is a small risk for death with surgery, loss of sexual function (approximately 37% higher risk), and loss of control of urination (approximately 11% higher risk) compared with no surgery. These risks may vary depending on patient and surgeon characteristics and treatment method.
9. The PSA test is not "just a blood test." It is a test that can open the door to more testing and treatment that a man may not actually want and that may actually harm him. A man's chances of being harmed are much greater than his chances of benefiting from the PSA test. Thus, each man should have the opportunity to decide for himself whether to have the PSA screening test.
10. Studies are ongoing, so clinicians expect to learn more about the benefits and harms of screening, and recommendations may change over time. Men are also welcome to change their minds at any time by asking for screening that they have previously declined or discontinue screening that they have previously requested.

Although ACP did not evaluate the evidence on the reliability, validity, or benefits of using available decision aids, some examples are listed in Table 2 in the original guideline document.

It is important for clinicians to convey to patients who may want to be screened that evidence indicates, at best, small benefits as well as substantial harms. Men who do not have a clear preference for screening should not be screened, and this should be documented. Clinicians should help men judge the balance of benefits and harms and discuss whether the harms outweigh the potential reduction in prostate cancer mortality in their particular cases. To frame the discussion, clinicians can inform patients that the PSA test will increase their lifetime risk for prostate cancer from approximately 9% to 16%. Currently, the tradeoff between harms and benefits beyond 11 to 13 years of follow-up is unknown. Alternatively, although 3 in 100 men will die of prostate cancer (or 5 in 100 for African American men), this means that 97 in 100 men (or 95 in 100 African American men) will die of something else. Finally, although some men may avoid pain and discomfort commonly associated with advanced disease, this must be balanced against the possibility of incontinence, erectile dysfunction, and other side effects that result from certain forms of aggressive treatment.

The goal of screening for any disease is to identify an undiagnosed condition for which an effective treatment is available, and timely treatment can lead to improved clinical outcomes. Although the best treatment approach for prostate cancer is unknown, current management for prostate cancer includes active surveillance, radical prostatectomy, external beam radiation therapy, and brachytherapy. Research is needed to better identify cancer that is more likely to benefit from curative treatments, in which case, benefits are more likely to outweigh harms.

High-Risk Patients

Screening in high-risk men has not been demonstrated to be associated with different outcomes than screening in average-risk men. Risks for prostate cancer include African American race and a first-degree relative diagnosed with prostate cancer, especially before age 65 years. Patients with such risks should receive information about the uncertainties, risks, and potential benefits associated with prostate cancer screening beginning at age 45 years. Shared decision making is important in making choices about prostate cancer screening in high-risk men as well. Men at appreciably higher risk (multiple family members diagnosed with prostate cancer before age 65 years) should receive this information beginning at age 40 years.

Frequency of Screening

Currently, no clear evidence is available to guide decisions about the periodicity or frequency of the evaluation of risk for prostate cancer or discussion about the benefits and harms. Considering the harms of screening and modest mortality benefit, increasing the interval between screening tests may reduce harms. The PLCO trial, which screened annually, found no benefit, whereas the ERSPC trial, in which most participants were screened every 4 years (range, 2 to 7 years), did find benefit, suggesting that longer intervals may be indicated.

Guidance Statement 2: ACP recommends that clinicians should not screen for prostate cancer using the prostate-specific antigen test in average-risk men under the age of 50 years, men over the age of 69 years, or men with a life expectancy of less than 10 to 15 years.

Increasing age or the presence of a chronic comorbid illness that affects life expectancy substantially limits the potential benefits of prostate cancer screening compared with harms. Evidence presented in the guidelines shows substantial harms associated with prostate cancer screening and treatment relative to questionable benefits. Any benefit is even smaller in men older than 69 years because the cancer may not become clinically significant in a person's lifetime. For men younger than 50 years, the harms, such as erectile dysfunction and urinary incontinence, carry even more weight relative to any potential benefit. Hence, the harms of screening for prostate cancer outweigh the benefits in average-risk men younger than 50 years, men older than 69 years, or men who have a life expectancy less than 10 to 15 years. Therefore, clinicians should not screen men younger than 50 years, those aged 70 years or older, or men with substantial comorbid conditions and a life expectancy less than 10 to 15 years.

The figure in the original guideline document summarizes the guidance statements and clinical considerations for prostate cancer screening.

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

Prostate cancer

Guideline Category

Counseling

Risk Assessment

Screening

Clinical Specialty

Family Practice

Internal Medicine

Oncology

Preventive Medicine

Intended Users

Physicians

Guideline Objective(s)

To critically review the available guidelines developed in the United States to help guide internists and other clinicians in making decisions about screening for prostate cancer

Target Population

Adult men

Interventions and Practices Considered

Screening for prostate cancer using the prostate-specific antigen (PSA) test:

- Informing men between the ages of 50 and 69 years about the benefits/harms of screening for prostate cancer
- Basing the decision to screen for prostate cancer on the risk for prostate cancer, a discussion of the benefits and harms of screening, the patient's general health and life expectancy, and patient preferences

Major Outcomes Considered

- Sensitivity and specificity of diagnostic tests (prostate-specific antigen [PSA] and digital rectal examination [DRE])
- Morbidity and mortality due to prostate cancer
- Harms of prostate cancer screening and related treatments
- Benefits and risks of prostate cancer screening in selected age groups

Methodology

Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

The Clinical Guidelines Committee of the American College of Physicians (ACP) began by searching the National Guideline Clearinghouse for guidelines on screening for prostate cancer (August 2012). They reviewed the titles and abstracts of each document. The committee excluded those that were obviously restating guidelines from other organizations. Four prostate cancer screening guidelines developed in the United States were selected: American College of Preventive Medicine (ACPM), American Cancer Society (ACS), American Urological Association (AUA), and U.S. Preventive Services Task Force (USPSTF).

Number of Source Documents

This guideline is adapted from 4 U.S. prostate cancer screening guideline sources.

Methods Used to Assess the Quality and Strength of the Evidence

Not stated

Rating Scheme for the Strength of the Evidence

Not applicable

Methods Used to Analyze the Evidence

Review

Description of the Methods Used to Analyze the Evidence

The selected prostate cancer screening guidelines were reviewed independently by 4 coauthors. The authors followed the Appraisal of Guidelines Research and Evaluation (AGREE) II collaboration method to produce this guidance statement. The AGREE II instrument asks 23 questions in 6 domains: scope and purpose, stakeholder involvement, rigor of development, clarity and presentation, applicability, and editorial independence. The authors selected 1 guideline to calibrate their scores on the 6 domains of the AGREE II instrument. The authors then scored each guideline independently, and the scores were compared (see Table 1 in the original guideline document). Although total quantitative scores varied, the qualitative assessment of guideline quality was consistent among the 4 reviewers; indeed, the overall rankings of the quality of the guidelines were similar.

Details of the American College of Physicians (ACP) guidance statement development process can be found in ACP's methods paper (see the "Availability of Companion Documents" field).

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

When several guidelines are available on a topic or existing guidelines conflict, the American College of Physicians (ACP) believes that it is more useful to provide clinicians with a rigorous review of the available guidelines rather than develop a new guideline on the same topic. Thus, the ACP Clinical Guidelines Committee developed this guidance statement for clinicians by assessing current guidelines developed by other organizations on screening for prostate cancer.

Rating Scheme for the Strength of the Recommendations

Not applicable

Cost Analysis

American College of Physicians High-Value Care Advice

High-value care reflects care for which the benefits are likely to outweigh the harms and costs associated with delivering such care. Screening with the prostate-specific antigen (PSA) test is low-value care. The value of screening for prostate cancer in most cases is low, given that the chances of harm with screening outweigh the chances of benefit for most men and that the direct and indirect costs associated with biopsy, repeated testing, aggressive therapy, patient anxiety, and missed work are significant.

Method of Guideline Validation

Description of Method of Guideline Validation

Approved by the American College of Physicians (ACP) Board of Regents on April 16, 2012.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The guidance statements are derived from other organizations' guidelines and are based on an evaluation of strengths and limitations of the available guidelines (see the "Adaption" field for full citations).

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

The small potential benefit of prostate cancer screening corresponds to preventing, at most, 1 death caused by prostate cancer per 1000 men screened after 11 years of follow-up.

Potential Harms

- The harms of prostate cancer screening are substantial and include false alarms (suggesting that a patient may have cancer when he does not) related to high false-positive rates associated with digital rectal examination (DRE) and especially the prostate-specific antigen (PSA) test, overdiagnosis (that is, detecting cancer that will not cause future morbidity and mortality), high false-negative rates, anxiety, and discomfort.
- Positive screening results may lead to further testing, such as biopsies, which not only can be painful but can also lead to complications, such as infections, as well as overtreatment and the harms associated with it. In addition, currently available treatments are associated with harms, such as urinary, gastrointestinal, and sexual problems, as well as potential cardiovascular events and death. Data from Prostate Cancer Intervention Versus Observation Trial (PIVOT) showed that men who had radical prostatectomy had an 11% increased risk for urinary incontinence and a 37% increased risk for erectile dysfunction. Harms specific to DRE include discomfort and rectal bleeding.

Qualifying Statements

Qualifying Statements

- Clinical guidance statements are "guides" only and may not apply to all patients and clinical situations. Thus, they are not intended to override clinicians' judgment. All American College of Physicians (ACP) clinical guidance statements are considered automatically withdrawn or invalid 5 years after publication, or once an update has been issued.
- The authors of this article are responsible for its contents, including any clinical or treatment recommendations.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Implementation Tools

Foreign Language Translations

Mobile Device Resources

Patient Resources

Resources

Staff Training/Competency Material

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Staying Healthy

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

Qaseem A, Barry MJ, Denberg TD, Owens DK, Shekelle P. Screening for prostate cancer: a guidance statement from the Clinical Guidelines Committee of the American College of Physicians. *Ann Intern Med.* 2013 May 21;158(10):761-9. [25 references] [PubMed](#)

Adaptation

This guideline is adapted from the following primary sources:

- Lim LS, Sherin K; American College of Preventive Medicine (ACPM) Prevention Practice Committee. Screening for prostate cancer in U.S. men ACPM position statement on preventive practice. *Am J Prev Med.* 2008;34:164-70.
- Wolf AM, Wender RC, Etzioni RB, Thompson IM, D'Amico AV, Volk RJ, et al; American Cancer Society Prostate Cancer Advisory Committee. American Cancer Society guideline for the early detection of prostate cancer: update 2010. *CA Cancer J Clin.* 2010;60:70-98.
- Greene KL, Albertsen PC, Babaian RJ, Carter HB, Gann PH, Han M, et al. Prostate specific antigen best practice statement: 2009 update. *J Urol.* 2009;182: 2232-41.
- U.S. Preventive Services Task Force. Screening for prostate cancer: U.S. Preventive Services Task Force recommendation statement. *Ann Intern Med.* 2008;149:185-91.

Date Released

Guideline Developer(s)

American College of Physicians - Medical Specialty Society

Source(s) of Funding

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Guideline Committee

American College of Physicians (ACP) Clinical Guidelines Committee

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Financial Disclosures/Conflicts of Interest

Dr. Barry: *Board membership and employment:* Informed Medical Decisions Foundation; *Royalties:* Health Dialog. Dr. Owens: *Support for travel to meetings:* ACP. Dr. Shekelle: *Consultancy:* ECRI Institute; *Employment:* Veterans Affairs; *Grants/grants pending (money to institution):* Agency for Healthcare Research and Quality, Veterans Affairs, Centers for Medicare & Medicaid Services, National Institute of Nursing Research, Office of the National Coordinator; *Royalties:* UpToDate.

All other authors have no disclosures.

Disclosures can also be viewed at www.acponline.org/authors/icnje/ConflictOfInterestForms.do?msNum=M12-2408 .

A record of conflicts of interest is kept for each Clinical Guidelines Committee meeting and conference call and can be viewed at www.acponline.org/clinical_information/guidelines/guidelines/conflicts_cgc.htm .

Guideline Status

This is the current release of the guideline.

Guideline Availability

Electronic copies: Available from the [Annals of Internal Medicine Web site](#) .

Print copies: Available from the American College of Physicians (ACP), 190 N. Independence Mall West, Philadelphia PA 19106-1572.

Availability of Companion Documents

The following are available:

- Qaseem A, Snow V, Owens DK, Shekelle P. The development of clinical practice guidelines and guidance statements of the American College of Physicians: summary of methods. *Ann Intern Med.* 2010 Aug 3;153(3):194-199. Electronic copies: Available from the [Annals of Internal Medicine Web site](#) .
- Screening for prostate cancer. Continuing Medical Education. Available from the [Annals of Internal Medicine Web site](#) .
- Prostate cancer screening recommendations. Video. Available from the [Annals of Internal Medicine Web site](#) .

Print copies: Available from the American College of Physicians (ACP), 190 N. Independence Mall West, Philadelphia PA 19106-1572.

A summary version of the guideline is available in Chinese from the [Annals of Internal Medicine Web site](#) .

A collection of Recommendation Summaries for all current American College of Physicians Clinical Guidelines is now available for Personal Digital Assistant (PDA) download from the [American College of Physicians Web site](#) .

Patient Resources

The following is available:

- Summaries for patients. Screening for prostate cancer: a guidance statement from the Clinical Guidelines Committee of the American College of Physicians. Electronic copies: Available from the [Annals of Internal Medicine Web site](#) .

Print copies: Available from the American College of Physicians (ACP), 190 N. Independence Mall West, Philadelphia PA 19106-1572.

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NGC Status

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